IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

VIVEVE, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. 2:16-CV-1189-JRG
	§	
THERMIGEN, LLC,	§	
THERMIAESTHETICS, LLC, &	§	
RED ALINSOD, M.D.,	§	
	§	
Defendants,	§	
	§	

MEMORANDUM OPINION AND ORDER

On October 18, 2017, the Court held a hearing to determine the proper construction of the disputed claim terms in United States Patent No. 8,961,511 ("the '511 Patent"). The Court has considered the arguments made by the parties at the hearing and in their claim construction briefs. (Dkt. Nos. 53, 57, & 62.) The Court has also considered the intrinsic evidence and made subsidiary factual findings about the extrinsic evidence. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005); *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The Court issues this Claim Construction Memorandum and Order in light of these considerations.

TABLE OF CONTENTS

I. BACKGROUND

The ’511 Patent was filed on February 7, 2007, issued on February 24, 2015, and is titled “Vaginal Remodeling Device and Methods.” The ’511 Patent is generally directed to a method “for tightening tissue of the female genitalia by heating targeted connective tissue with radiant energy, while cooling the mucosal epithelial surface over the target tissue to protect it from the heat.” ’511 Patent at Abstract. The specification further states that “[t]he effect of the applied heat is to remodel genital tissue by tightening it,” and that “[t]he tightening may be a consequence of thermal denaturation of collagen as well as a longer term healing response in the tissue that includes an increased deposition of collagen.” *Id.* The specification indicates that the method covered by the ’511 Patent provides an alternative to invasive surgical procedures, which “can bring with them a risk of scarring that is entirely counterproductive with regard to the desired result.” *Id.* at 2:9–21.

Claim 1 of the ’511 Patent is an exemplary claim and recites the following elements (disputed term in italics):

> 1. *A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue*, the method comprising:
> *heating the target tissue*, and
> *remodeling the therapeutic zone of target tissue*, wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus.

II. APPLICABLE LAW

A. Claim Construction

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*,

381 F.3d 1111, 1115 (Fed. Cir. 2004)). To determine the meaning of the claims, courts start by considering the intrinsic evidence. *Id.* at 1313; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861. The general rule—subject to certain specific exceptions discussed *infra*—is that each claim term is construed according to its ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the patent. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003); *Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1347 (Fed. Cir. 2014) ("There is a heavy presumption that claim terms carry their accustomed meaning in the relevant community at the relevant time.") (vacated on other grounds).

"The claim construction inquiry . . . begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). "[I]n all aspects of claim construction, 'the name of the game is the claim.'" *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1298 (Fed. Cir. 2014) (quoting *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998)). First, a term's context in the asserted claim can be instructive. *Phillips*, 415 F.3d at 1314. Other asserted or unasserted claims can also aid in determining the claim's meaning, because claim terms are typically used consistently throughout the patent. *Id.* Differences among the claim terms can also assist in understanding a term's meaning. *Id*. For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. *Id*. at 1314–15.

"[C]laims 'must be read in view of the specification, of which they are a part.'" *Id*. (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc)). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id*. (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). But, "'[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.'" *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)); *see also Phillips*, 415 F.3d at 1323. "[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004).

The prosecution history is another tool to supply the proper context for claim construction because, like the specification, the prosecution history provides evidence of how the U.S. Patent and Trademark Office ("PTO") and the inventor understood the patent. *Phillips*, 415 F.3d at 1317. However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* at 1318; *see also Athletic Alternatives, Inc. v. Prince Mfg.*, 73 F.3d 1573, 1580 (Fed. Cir. 1996) (ambiguous prosecution history may be "unhelpful as an interpretive resource").

Although extrinsic evidence can also be useful, it is "'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id*. at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition are entirely unhelpful to a court. *Id*. Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id*. The Supreme Court recently explained the role of extrinsic evidence in claim construction:

> In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. *See, e.g.*, *Seymour v. Osborne*, 11 Wall. 516, 546 (1871) (a patent may be "so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning"). In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the "evidentiary underpinnings" of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

III. CONSTRUCTION OF AGREED TERMS

The parties agreed to the construction of the following terms/phrases:

Claim Term/Phrase	**Agreed Construction**
"epithelium" (Claims 1, 5, 17, 19, 35, 37, 40, 43, 45, 48, 51, 53, 56)	"surface layer tissue"

"mucosal epithelium" (Claims 23, 24)	"mucous surface layer tissue"
"energy delivery element" (Claims 5, 17, 37, 40, 45, 48, 53, 56)	No construction necessary—plain and ordinary meaning

(Dkt. No. 63 at 2). In view of the parties' agreement on the proper construction of the identified terms, the Court **ADOPTS** the parties' agreed constructions.

IV. CONSTRUCTION OF DISPUTED TERMS

The parties' dispute focuses on the meaning and scope of three phrase in the '511 Patent.

A. "heating the target tissue"

Disputed Term	Plaintiff's Proposal	Defendants' Proposal
"heating the target tissue"	Plain and ordinary meaning.	"heating the collagen tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium"

1. The Parties' Positions

The parties dispute whether the phrase "heating the target tissue" requires heating the tissue to a "to a temperature that is higher than the temperature of the epithelium," as Defendants contend. Plaintiff argues that Defendants' construction seeks to add two limitations to the phrase that are not recited in the claims, and are inconsistent with the remaining intrinsic evidence. (Dkt. No. 53 at 8). According to Plaintiff, the independent claims only require the target tissue to be heated. (*Id.* at 9). Plaintiff further argues that the temperature of the target tissue before the physician begins treatment may be the reference point for determining whether the tissue has been heated. *Id.* Plaintiff also contends that the additional technique of "cooling" the epithelium may be employed to create a reverse thermal gradient in certain embodiments. *Id.* (citing '511 Patent at 13:30–45).

Plaintiff also argues that the claims asserted against Defendants do not include an epithelium limitation, and that limitation is expressly recited in other claims. (Dkt. No. 53 at 9) (citing ’511 Patent at Claims 9 and 15). According to Plaintiff, the specification cannot overcome the claim language because it repeatedly describes cooling as “embodiments of the invention.” (Dkt. No. 53 at 10) (citing ’511 Patent at 13:27, 13:30–31, 13:37–38). Plaintiff also contends that Defendants’ construction improperly limits the “target tissue” to “collagen.” (Dkt. No. 53 at 10). According to Plaintiff, Defendants’ construction is contrary to the specification because it describes “target tissue” as including both collagen and muscularis. *Id.* (citing ’511 Patent at 3:43-47).

Defendants respond that the methods of the ’511 Patent expressly “build on those of [the] prior art such as those described by Knowlton [’316].” (Dkt. No. 57 at 14) (citing ’511 Patent at 5:65–67). According to Defendants, the Knowlton prior art describes methods for heating and cooling target tissue simultaneously, i.e., creating a reverse thermal gradient in order to protect the epithelial surface. (Dkt. No. 57 at 14). Defendants argue that the surface tissue temperature is purposefully maintained lower than that of the underlying “target tissue” so as to provoke subdermal remodeling, without effecting any thermally-induced change to the surface tissue. *Id.* (citing Dkt. No. 57-2 at claims 1, 20, 22-24; Dkt. No. 57-3 at claims 1, 17). Defendants contend that the principle of reverse thermal gradient is an inextricable part of the invention of Knowlton, and the same must be true of the ’511 Patent. (Dkt. No. 57 at 14).

Defendants further argue that every single embodiment of the method described in the specification requires that heating be accompanied by cooling. (*Id.* at 15) (citing ’511 Patent at 4:40–43). Defendants contend that the overlaying mucosal epithelium does not get heated to the same temperatures as the underlying “target tissue” because the overlaying mucosal epithelium is

cooled. (Dkt. No. 57 at 15). Defendants also argue that the '511 Patent is clear that its claimed methods are non-invasive and substantially non-ablative of genital tissue and its goal is to eliminate the risk of scarring. *Id.* Defendants contend that these advantages cannot be achieved unless the claims are construed to differentiate between the lower temperature of the epithelium from the higher temperature of tissue to be remodeled underlying the epithelium. (*Id.* at 16). Defendants argue that the term "heating the target tissue" should be construed so that the heat is applied to the tissue underlying the surface mucosal epithelium, without ablation or the risk of scarring of the epithelial surface. *Id.* (citing '511 Patent at 11:27–29).

Defendants also argue that requiring the surface tissue temperature to be lower than the underlying tissue during the application of energy (*i.e.*, heating) is a necessary aspect of the invention. (Dkt. No. 57 at 16). Defendants contend that the heating step of the claims must differentiate between tissue temperatures. *Id.* Defendants argue that the cooling and creation of the reverse thermal gradient are key to the invention as a whole. *Id.* Regarding Plaintiff's claim differentiation argument, Defendants argue that their construction would not render the dependent claims redundant. (*Id.* at 17).

Plaintiff replies that the claims are silent as to the temperature of the surface tissue. (Dkt. No. 62 at 5). Plaintiff also argues that Defendants' construction would also violate the rule that "particular embodiments will not be read into the claims where the claim language is broader than the embodiments," as well as the doctrine of claim differentiation. *Id.* (citing *Plano Encryption Techs., LLC v. Alkami, Inc.*, 2017 U.S. Dist. LEXIS 135518 at *7 (E.D. Tex. Aug. 23, 2017)). Plaintiff also contends that building on the teachings of Knowlton does not mean that all aspects of the Knowlton treatments must become part of the claimed invention. (Dkt No. 62 at 5). According to Plaintiff, the '511 Patent is clear that the inventor built on Knowlton by disclosing

novel methods "configured and adapted to particulars of the female genital treatment site." *Id.* (citing '511 Patent at 5:65–6:4). Plaintiff argues that the "build on" passage does not identify either the surface cooling or reverse thermal gradient as the improved features nor as a necessary part of the invention. (Dkt. No. 62 at 5).

Plaintiff further argues that there are strong indicia that the patentee did not intend to limit the claims to cooling or a reverse thermal gradient. (*Id.* at 6). According to Plaintiff, the specification repeatedly and consistently describes the surface tissue cooling and thermal gradient features as mere embodiments of the invention. *Id.* Plaintiff also contends that the '511 Patent recites these features in dependent claims. *Id.* Plaintiff further argues that Defendants cite no evidence that cooling the surface tissue is actually necessary to improve the likelihood that the surface tissue is not damaged. (*Id.* at 7). Finally, Plaintiff contends that cooling the surface tissue does not necessarily ensure that the goals of the invention are achieved. *Id.*

For the following reasons, the Court finds that the phrase **"heating the target tissue"** should be construed to mean **"heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium."**

2. Analysis

The phrase "heating the target tissue" appears in claims 1, 2-4, 15, 35, 36, 43, 44, 51, and 52 of the '511 Patent. The Court finds that the phrase is used consistently in the claims and is intended to have the same general meaning in each claim. The Court further finds that the intrinsic evidence indicates that a critical aspect of the invention is the manner in which the target tissue is heated. Specifically, the intrinsic evidence indicates that maintaining the epithelium at a temperature lower than the underlying tissue is important to ensure that the epithelium is not damaged or substantially modified by the method. In other words, "[e]mbodiments of the invention

provide a method and apparatus for creating a reverse thermal gradient that utilizes one or more RF electrodes 30, to convey energy that manifests as heat in the target tissue, and a mechanism to cool the epithelial surface above the targeted underlying layers." '511 Patent at 13:12–16, *see also id.* at 13:43–45 ("Thus, a reverse thermal gradient is created, with a lower temperature at the mucosal epithelium, and a higher temperature in the underlying tissue.").

The Background section states that a problem with surgical approaches is that they "can bring with them a risk of scarring that is entirely counterproductive with regard to the desired result" *Id.* at 2:11–12. To address this shortcoming, the specification discloses embodiments that cool the epithelial surface to protect it from the heat. For example, the Abstract states that "*[t]his invention* relates generally to apparatus and methods for tightening tissue of the female genitalia by heating targeted connective tissue with radiant energy, *while cooling the mucosal epithelial surface over the target tissue to protect it from the heat*." *Id.* at Abstract (emphasis added).

Similarly, the Summary of the Invention section states that "[t]he method includes contacting the mucosal epithelium with a treatment tip that has an energy delivering element and *a cooling mechanism*." *Id.* at 4:7–9 (emphasis added). The specification further adds that "[b]y delivering energy to the tissue *while cooling the epithelial surface*, a reverse thermal gradient is created." *Id.* at 4:9–13 (emphasis added). The specification describes the reverse thermal gradient as "*a lower temperature at the mucosal epithelium, and a higher temperature in the underlying tissue*." *Id.* at 13:43–45 (emphasis added). The specification explains that "[i]nasmuch as the overlaying mucosal epithelium *is cooled by the method, it does not get heated,* and is substantially unaffected by the method." *Id.* at 4:60–62 (emphasis added). In other words, "[t]he epithelial surface is thus a conduit for energy passing through to underlying layers, *but the energy does not manifest in the form of increased temperature at the epithelial surface*. As such, *the epithelium*

itself is not damaged or substantially modified by the method." *Id.* at 13:19–23 (emphasis added). Accordingly, the intrinsic evidence indicates that "heating the target tissue" should be construed to mean "heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium."

Defendants' construction further qualifies the "target tissue" as "collagen tissue." During the claim construction hearing, Defendants indicated that the "collagen tissue" limitation did not appear to be material to the parties' dispute. Notwithstanding, the Court rejects this aspect of Defendants' construction. The specification states that "[t]he target tissue lies immediately beneath the mucosal epithelium of genital tissues, and includes the lamina propria, a connective tissue that includes collagen in the extracellular space, and the muscularis, which includes smooth muscle." *Id.* at 3:43–47. The specification further states that "[t]he target zone of embodiments of the invention does not include deeper tissue, such as endopelvic fascia." *Id.* at 3:47–48. Thus, the specification indicates that the target tissue is not limited to "collagen tissue," but may also include the lamina propria and the muscularis. Accordingly, the Court rejects this aspect of Defendants' construction.

Plaintiff argues that Defendants' construction must be rejected because the claim language is broader than the embodiments. The Court is cognizant that to impose a limited construction, it is "not enough that the only embodiments, or all of the embodiments, contain a particular limitation." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). However, as indicated above, the intrinsic evidence indicates that a critical aspect of the invention is the manner in which the target tissue is heated. In particular, "heating the target tissue" means "heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium." *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005)

("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.").

Plaintiff also argues that the concepts of "cooling" and "reverse thermal gradient" are expressly recited in other dependent claims. (Dkt. No. 53 at 9-10). For example, claim 9 recites "the method further comprises cooling the epithelium," and claim 15 recites "heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue." The disputed phrase is "heating the target tissue," and the Court's construction addresses the manner in which the target tissue is "heated." The Court's construction does not limit the phrase to the cooling discussed in the dependent claims.

Moreover, the doctrine of claim differentiation "only creates a presumption that each claim in a patent has a different scope; it is not a hard and fast rule of construction." *Kraft Foods, Inc. v. International Trading Co.*, 203 F.3d 1362, 1368 (Fed. Cir 2000) (internal quotations omitted). Even if there is overlap, the claim differentiation argument is overcome by the intrinsic evidence, which requires that it is the target tissue below the epithelium that is heated while the epithelial surface remains cool. In other words, "the doctrine of claim differentiation does not serve to broaden claims beyond their meaning in light of the specification, and does not override clear statements of scope in the specification and the prosecution history." *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1302 (Fed. Cir. 1999) (citation omitted); *see also Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1323 (Fed. Cir. 2016) ("Although it is a useful tool, claim differentiation does not require that the 'dependent claim tail . . . wag the independent claim dog' in this case.") (citing *N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1577 (Fed. Cir. 1993)). As discussed above, the intrinsic evidence indicates that the proper scope of the phrase "heating the target tissue" is "heating the tissue underlying the epithelium to a temperature

that is higher than the temperature of the epithelium."

Finally, during the claim construction hearing, and in a footnote in its reply, Plaintiff argued that the "heating without cooling is enabled because the original claims as well as the specification discusses heating without reference to cooling." (Dkt. No. 62 at 7 n.3) (citing '511 Patent at 14:9–15:15). The specification states that "[i]n typical embodiments of the invention, the method provides for surface cooling *coincident with the time that heat is being delivered to underlying tissue*." '511 Patent at 14:9–11 (emphasis added). The specification further states that for other embodiments the method may include cooling before, after, or both before and after the application of heat. *Id.* at 14:11–17. However, the specification indicates that this cooling is "*in addition* to cooling the surface *while heating the underlying tissue.*" *Id.* (emphasis added). For the reasons discussed above, the intrinsic evidence indicates that the proper scope of "heating the target tissue" is "heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium."

3. Court's Construction

The Court construes the phrase **"heating the target tissue"** to mean **"heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium."**

B. "remodeling the therapeutic zone of target tissue"

Disputed Term	Plaintiff's Proposal	Defendants' Proposal
"remodeling the therapeutic zone of target tissue"	"uniform delivery of energy to achieve a therapeutic temperature of a portion of the target tissue that causes tightening or contracting without damaging the mucosal epithelium"	"tightening or contracting the collagen tissue underlying the epithelium of female genital tissue"

1. The Parties' Positions

The parties agree that "remodeling" the target tissue includes at least "tightening or contracting" of the target tissue. (Dkt. No. 57 at 17). The parties dispute whether the phrase should be construed to include the limitations of "uniform delivery of energy" and "without damaging the mucosal epithelium," as Plaintiff proposes. Plaintiff contends that its construction identifies the "specific concrete steps," the "specific tissue," and the "particularized conditions" that define remodeling in the '511 Patent. (Dkt. No. 53 at 14). Plaintiff argues that the "specific concrete steps" of "remodeling" include the uniform delivery of energy to heat the target tissue. *Id.* (citing '511 Patent at 2:60–62, 8:15–18).

Plaintiff further argues that the "specific tissue" for "remodeling" is the "therapeutic zone." (Dkt. No. 53 at 14). According to Plaintiff, the specification defines the therapeutic zone as "that portion of the target tissue which attains the therapeutic temperature, for a sufficient time." *Id.* (citing '511 Patent at 11:23–25, 4:14–16). Plaintiff also argues that the "particularized conditions" for "remodeling" include tightening or contracting the tissue without "damaging the mucosal epithelium." (Dkt. No. 53 at 15) (citing '511 Patent at 5:9–11, 2:11–18, 2:60–62, 12:19–21, 2:9–16).

Defendants respond that "remodeling," "therapeutic zone," and "target tissue" are all defined terms in the specification. (Dkt. No. 57 at 18) (citing '511 Patent at 4:14–16, 3:43–48, 13:2–5). Defendants further argue that the "phenomenon" of remodeling is the necessarily passive effect or result caused when heated tissue reaches a sufficient temperature. (Dkt. No. 57 at 18) (citing '511 Patent at 4:14–16, 5:2–5, 11:21–23). Defendants contend that Plaintiff now seeks to redefine and expand the scope of the term with the importation of additional language. (Dkt. No. 57 at 18). According to Defendants, the insertion of the terms "uniform delivery of energy" and "without damaging the mucosal epithelium" are not required and do not make sense as appended

to this claim term. (*Id.* at 19).

Defendants further argue that if Plaintiff's construction was adopted, the independent claims of the '511 Patent would provide twice for the separately-recited heating step. *Id.* Defendants contend that it would be illogical to modify this passive step with an additional active step of "uniform delivery" that is not defined in terms of a method by the patent disclosure. *Id.* According to Defendants, there is no description as to how uniform delivery is accomplished other than by reference to the unclaimed apparatus. *Id.* Defendants argue that the term "target tissue" is central to the "remodeling" term and is defined as distinct and physically separate from the epithelium. *Id.*

Defendants also contend that Plaintiff's limitations would be more appropriately added to the heating step. (*Id.* at 19-20). According to Defendants, the specification consistently ties preventing damage to the "heating step," not the "remodeling" step as Plaintiff proposes. (*Id.* at 20) (citing '511 Patent at 2:60–62, 8:8–15, 8:18–22, 13:16–26). Defendants further argue that Plaintiff's construction renders the scope of the claim more ambiguous and would not be helpful to a jury. (Dkt. No. 57 at 20). According to Defendants, the specification provides no guidance on what exactly constitutes "uniform delivery" or "damage" of the mucosal epithelium. *Id.*

Plaintiff replies that if Defendants' construction is adopted, the "remodeling" limitation would encompass the prior art techniques that the inventor was improving. (Dkt. No. 62 at 9). Plaintiff argues that the specification makes clear that "uniform delivery of energy" is integral to the specification's definition of remodeling and damage prevention. *Id.* ('511 Patent at 2:60–62, 8:18–19). Finally, Plaintiff argues that its construction actually narrows the scope of "remodeling" according to the specification's description of this technique. (Dkt. No. 62 at 10). Plaintiff contends that the specification provides guidance on the concepts of "uniform delivery of energy"

and "without damaging the mucosal epithelium." *Id.* (citing '511 Patent at 2:56–60, 13:22–23, 12:19–21).

For the following reasons, the Court finds that the phrase **"remodeling the therapeutic zone of target tissue"** should be construed to mean **"causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature."**

2. Analysis

The phrase "remodeling the therapeutic zone of target tissue" appears in claims 1, 35, 43, and 51 of the '511 Patent. The Court finds that the phrase is used consistently in the claims and is intended to have the same general meaning in each claim. The Court agrees with the parties that "remodeling" includes at least "tightening or contracting" of the target tissue. The specification states that "[r]emodeling of genital tissue, as practiced by embodiments of this invention, may be understood variously as *contracting or tightening of tissue*." '511 Patent at 13:2–4 (emphasis added). The specification also states that "[w]hether by denaturation of existing collagen, or by later deposition of new collagen, the effect of remodeling on the tissue is generally *one of tissue contraction or tightening*." *Id.* at 5:2–5 (emphasis added). The specification further indicates that the time the remodeling may occur can vary. Specifically, the specification states that "[r]emodeling of target tissue within the therapeutic zone may occur substantially during the time when the tissue is being heated. Remodeling may also occur substantially after the heating has occurred, for example days or weeks later." *Id.* at 4:63–66. Accordingly, the Court finds that "remodeling" includes at least "tightening or contracting" of the target tissue.

The Court further finds that "remodeling" includes the step of heating a zone of tissue within the target tissue to a therapeutic temperature. The specification describes the "therapeutic

zone" as a zone of tissue within the target tissue that is heated to a therapeutic temperature. '511 Patent at 4:14–22 ("A zone of tissue that is heated within the target tissues to a threshold level, i.e., to a therapeutic temperature that causes remodeling is termed a therapeutic zone."). In one embodiment, the specification states that the "[t]emperature is raised to a level that is therapeutic, i.e., to a temperature that causes remodeling, as described herein." *Id.* at 11:21–23. The specification further states that "[t]he therapeutic temperature, in some cases may be only as high as 45 degrees C., or as high as 80 degrees C." *Id.* at 11:25–27. The specification adds that the "portion of the target tissue which attains the therapeutic temperature, for a sufficient time, is termed the therapeutic zone within the target tissue." *Id.* at 11:23–25. Accordingly, the intrinsic evidence indicates that the phrase "remodeling the therapeutic zone of target tissue" should be construed to mean "causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a threshold level."

To support the additional limitations of "uniform delivery of energy" and "without damaging the mucosal epithelium," Plaintiff argues that its construction tracks the Court's previous findings "that remodeling includes a doctor's application of 'specific concrete steps to specific tissue under particularized conditions.'" (Dkt. No. 53 at 13-14, 62 at 8) (citing Dkt. No. 43 at 7). The Court first notes that Plaintiff overgeneralizes the Court's previous findings. In responding to Defendants' Motion to Dismiss, it was Plaintiff that argued that "remodeling is a process comprising a doctor's application of specific concrete steps to specific tissue under particularized conditions, which is simply predicated on the ability of collagen to be physically transformed by heat." (Dkt. No. 43 at 7). In denying the Motion, the Court agreed with Plaintiff's argument. However, the Court further clarified that it is the claims that "provide examples of how the '511 patent dictates, with specificity, the concrete steps which a doctor should take in

performing the claimed method." (Dkt. No. 43 at 9-10). In other words, the claim language itself indicates that remodeling includes a doctor's application of "specific concrete steps to specific tissue under particularized conditions." (Dkt. No. 62 at 8).

Furthermore, the Court rejects Plaintiff's construction because the terms "uniform delivery of energy" and "without damaging the mucosal epithelium" are unwarranted and would confuse the claim language. First, Plaintiff's construction would create a duplicative and redundant heating step. Claim 1 separately recites "heating the target tissue," and Plaintiff's "uniform delivery of energy" is "heating," which would be redundant of the previously recited "heating" step. Moreover, the disputed phrase is directed towards causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature. Indeed, the specification states that "[n]ot all tissue within the target tissue necessarily reaches this threshold level of heat. In some cases, cooling from the treatment tip may penetrate into the target tissue, and in this situation, the presence of cooled tissue may have an effect on the therapeutic zone, by moving it deeper within the target tissue, for example, or by constraining its volume." '511 Patent at 4:16–22.

For example, Figure 8 illustrates a therapeutic zone of target tissue beneath contact site 102. '511 Patent at 14:24–29 ("Also shown below the contact site 102 (with dotted lines) are target tissue layers, the lamina propria 104 and the muscularis 106. In typical embodiments of the invention, the method includes making contact with the epithelium, delivering energy, and then moving the treatment tip to another contact site, and delivering energy there.")

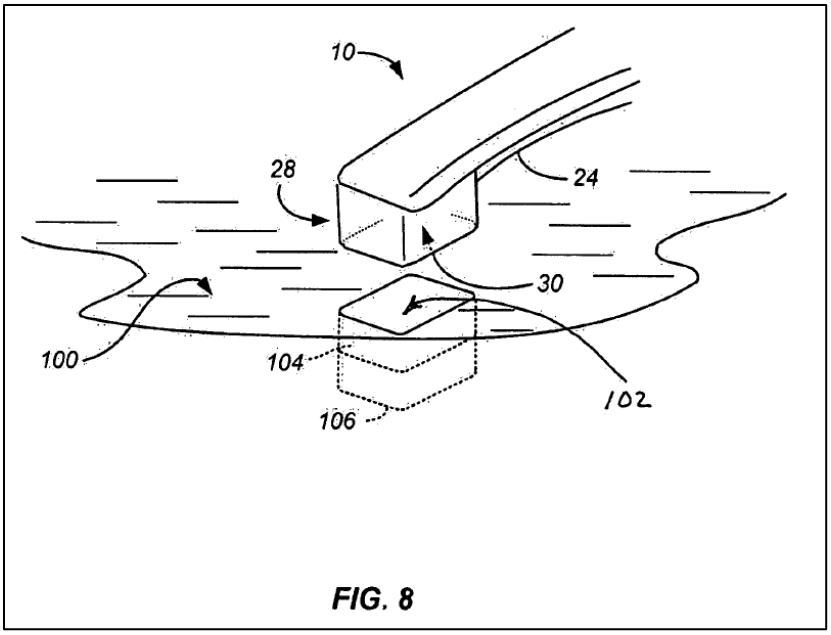

FIG. 8

'511 Patent at Figure 8. Plaintiff's proposed "uniform delivery of energy" does nothing to clarify causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature.

Similarly, the limitation of "without damaging the mucosal epithelium" is captured by the recited step of "heating the target tissue." As discussed above, a person of ordinary skill in the art would understand that "heating the target tissue" means "heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium." In other words, "[t]he epithelial surface is thus a conduit for energy passing through to underlying layers, *but the energy does not manifest in the form of increased temperature at the epithelial surface*. As such, *the epithelium itself is not damaged or substantially modified by the method*." '511 Patent at 13:19–23 (emphasis added). Finally, Plaintiff's proposed limitations would introduce unwarranted ambiguity into the claim language. A jury could be confused or mislead on what exactly constitutes "uniform delivery of energy" or "without damage" of the mucosal epithelium.

Turning to Defendants' construction, the Court rejects it because it is overly broad.

Defendants' construction reads the "therapeutic zone" out of the claim, and allows the "remodeling" to apply to any collagen tissue underlying the epithelium. As recited in the claims and indicated in the specification, the "therapeutic zone" is a zone within the target tissue. For example, the specification states that "[n]ot all tissue within the target tissue necessarily reaches this threshold level of heat. In some cases, cooling from the treatment tip may penetrate into the target tissue, and in this situation, the presence of cooled tissue may have an effect on the therapeutic zone, by moving it deeper within the target tissue, for example, or by constraining its volume." '511 Patent at 4:16–22. Defendants' construction incorrectly reads the "therapeutic zone" out of the claims, by equating the zone with any collagen tissue underlying the epithelium. As discussed above, the "therapeutic zone" is a zone of tissue within the target tissue that is heated to a therapeutic temperature.

As with the previous term, the Court also rejects Defendants' construction because it further qualifies the "target tissue" as "collagen tissue." The specification states that "[t]he target tissue lies immediately beneath the mucosal epithelium of genital tissues, and includes the lamina propria, a connective tissue that includes collagen in the extracellular space, and the muscularis, which includes smooth muscle." *Id.* at 3:43–47. Thus, the specification indicates that the "therapeutic zone" is not limited to "collagen tissue."

3. Court's Construction

The Court construes the phrase **"remodeling the therapeutic zone of target tissue"** to mean **"causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature."**

C. Preamble: "A method for remodeling . . ."

Disputed Term	Plaintiff's Proposal	Defendants' Proposal
Preamble: "A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue,"	Preamble is limiting, all words having plain and ordinary meaning except as construed or agreed to by the parties	A method of tightening or contracting the collagen tissue underlying the epithelium of female genital tissue including but not limited to* at least one of vulva, introitus and vagina tissue * "Comprising" is an open ended patent claim term.

1. The Parties' Positions

The parties dispute whether the "target tissue" must include tissue of the vulva, introitus, and vagina, as Plaintiff contends, or if "comprising" means that the scope of the claims include "remodeling of any female genital tissue," as Defendants contend. Plaintiff argues that every independent claim of the '511 Patent includes the same preamble, and that the preamble provides the antecedent basis for claim elements recited in the body of the independent claims. (Dkt. No. 53 at 16). Plaintiff also contends that Defendants' construction is wrong because it incorporates its incorrect proposal for the phrase "remodeling." *Id.*

Defendants respond that the examiner rejected the claims of the application as anticipated by and obvious over the Knowlton reference, because that reference disclosed remodeling of female genital tissue, specifically the cervix. (Dkt. No. 57 at 21). Defendants contend that the patentee amended the claims to include heating the underlying tissue of at least one of three specific locations of the female genitalia: the vulva, introitus, and vagina. *Id.* (citing Dkt. No. 57-9; Dkt. No. 57-10). According to Defendants, this amendment does not reflect a limitation to the preamble of the independent claims as issued because the term "comprising" covers the remodeling of any female genital tissue. (*Id.* at 22).

Plaintiff replies that the language of the preamble requires no construction beyond the phrase "remodeling a therapeutic zone within a target tissue." (Dkt. No. 62 at 10). Plaintiff

contends that the remaining terms of the preamble have well known definitions that would be readily apparent to a person of ordinary skill in the art. *Id.* According to Plaintiff, the '511 Patent is clear that its methods apply only to certain areas of genital tissue. *Id.* Plaintiff contends that those areas are specifically called out respectively in the independent claims. *Id.* Plaintiff further contends that the target tissue must include tissue of the vulva, introitus and vagina. (*Id.* at 10).

For the following reasons, the Court finds that the preamble limits the claims by requiring the target tissue to include tissue underlying an epithelium of female genital tissue that includes at least one of vulva, introitus and vagina tissue.

2. Analysis

The disputed preamble appears in claims 1, 35, 43, and 51 of the '511 Patent. The Court finds that the preamble is used consistently in the claims and is intended to have the same general meaning in each claim. The claim language of the preamble is not confusing or ambiguous. Instead, the dispute centers on the weight that should be given to the amendments made to the preamble during prosecution. During prosecution, the examiner rejected all claims as either anticipated by or obvious over U.S. Patent No. 6,350,276 ("Knowlton '276"). (Dkt. No. 57-6). The examiner argues that Knowlton "discloses a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue (as in the embodiment of figures 13-14 describing the treatment of cervix, see col. 13; 35-37) . . . ." (Dkt. No. 57-8 at 3-16). The examiner explained that Knowlton discloses treatment directed to at least the cervix, which is part of "female genital tissue," and therefore no claim was allowable due to their scope as inclusive of all female genital tissue. *Id.*

In response to the examiner's rejections regarding the Knowlton '276 disclosure, the patentee amended claim 1 as follows:

> 1. (Currently amended) A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying ~~a mucosal~~ an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:
>
> heating the target tissue, and
>
> remodeling the therapeutic zone of target tissue.

(Dkt. No. 57-9 at 3). The patentee argued that "Claim 1, as amended, recites a method for remodeling a therapeutic zone within a target tissue, the tissue including at least one of vulva, introitus, and vagina tissue. Knowlton does not disclose a method for remodeling a therapeutic zone including at least one of vulva, introitus or vagina." (Dkt. No. 57-9 at 10).

In the February 13, 2014 Office Action, the examiner disagreed that the amended preamble overcame the rejection.[1] The examiner argued that "while the claim may recite at least one of a vagina, introitus or vulva tissue are part of the target tissue, the other tissue treated in Knowlton are also considered as part of the female genital tissue. The Examiner is also of the position that claim 1, as presently recited, fails to specifically require that those portions (vulva, vagina or introitus tissue) comprising the target tissue are actually required to be either heated or remodeled by the claim." (February 13, 2014 Office Action at 13). The examiner further stated the following:

> It is the Examiner's position that the Applicant's amendments to each of claims 1 and 41 to which attempt further specify the type of tissue forming at least a part of the therapeutic zone fail to positively require that any of the tissue of the vulva, the introitus or the vagina is actually required to be heated and/or remodeled per claim 1. Similarly, the Examiner does not believe that the apparatus of claim 41 need to treat any of the tissue of the vulva, the introitus or the vagina. That is, the Examiner is of the position that the embodiment of figures 13-14 with the description of the treatment of cervix in col. 13; 35-37, fairly provides for the claimed method and

[1] The parties did not include the February 13, 2014 Office Action in the record before the Court. The Court finds that the February 13, 2014 Office Action is an important part of the prosecution history. Indeed, it is the examiner's direct response to the arguments made by the patentee after amending the preamble. Accordingly, as indicated during the claim construction hearing, the Court takes judicial notice of the February 13, 2014 Office Action, which can be found at https://portal.uspto.gov/pair/PublicPair, and is entered with this Order as Court Exhibit A.

apparatus."

(February 13, 2014 Office Action at 14). The examiner further explained that "[t]his lack of a positive requirement of the treatment of the presently-recited areas in claims 1 and 41 *is due in part to each limitation's positioning within the preamble of each [ ] claim,* to the claiming that it is the female genital tissue which is comprising the tissue of the vagina, introitus or vulva, *and to the lack of a close end to the tissue which can comprise the therapeutic zone.*" (February 13, 2014 Office Action at 15) (emphasis added). The examiner indicated that claims 26-29 were allowable "due to the fact that each actually requires the treatment of a portion of the female genital tissue (via heating a specific portion) which is not taught by Knowlton (i.e. not the cervix). Such positive claiming can be used as a guideline when drafting subsequent language." (February 13, 2014 Office Action at 15).

In the June 9, 2014 Office Action Response, the patentee amended the claims as suggested by the examiner. For example, claim 1 was amended as follows:

> 1. (Currently amended) A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:
>
> heating the target tissue, and
>
> remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from about 1 cm to about 3.5 cm in from the introitus.

(Dkt. No. 57-10 at 3). The patentee argued that "[b]y this response, claim 1 has been amended to incorporate the allowable subject matter of claim 26, including all of the limitations of the base claim and any intervening claims. Further, claims 27, 28 and 29 have all been re-written as independent claims, including all of the limitations of the base claim and any intervening claims." (*Id.* at 10). In the October 9, 2014 Office Action Response, the patentee further amended the

independent claims to remove "about" to overcome a 35 U.S.C. § 112(b) rejection. (Dkt. No. 57-11 at 3, 6, 12). In the "Reasons for Allowance," the examiner stated that "[Knowlton '276] fails to contemplate the specific areas of treatment set forth in independent claims 2 and 27-29. No other reference has been found which discloses, fairly suggests or makes obvious this area of treatment whether taken alone or in combination with the Knowlton ['276]." (Dkt. No. 57-12 at 3).

As indicated above, the examiner found that the amendment to the preamble failed "to positively require that any of the tissue of the vulva, the introitus or the vagina is actually required to be heated and/or remodeled per claim 1." (February 13, 2014 Office Action at 14). The examiner explained that "[t]his lack of a positive requirement of the treatment of the presently-recited areas in claims 1 and 41 *is due in part to each limitation's positioning within the preamble of each [ ] claim, . . . and to the lack of a close end to the tissue which can comprise the therapeutic zone.*" (February 13, 2014 Office Action at 15) (emphasis added). Thus, the examiner determined that the amended preamble failed to limit the heating/remodeling of the tissue to the vulva, the introitus or the vagina. Therefore, to the extent that a party contends that the preamble limits the claims to remodeling/heating of *only* the vulva, the introitus or the vagina tissue, the Court rejects that argument.

However, as indicated in the prosecution history, the remaining claim language does limit the claims to "specific areas of treatment set forth in [the] independent claim[s]." (Dkt. No. 57-12 at 3). In addition, the plain language of the claim indicates that "the target tissue" includes the "at least one tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue." Accordingly, the Court finds that the preamble is limiting to the extent that it requires "the target tissue" to include "tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue."

That said, the Court agrees with Defendants that the use of "comprising" in the preamble indicates that the "target tissue" includes, but is not limited to, "tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue." *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1327 (Fed. Cir. 1999) ("The transitional term 'comprising' . . . is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.") (citing *In re Gray*, 53 F.2d 520 (CCPA 1931)). "A drafter uses the term 'comprising' to mean 'I claim at least what follows and potentially more.'" *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1383 (Fed. Cir. 2000). Indeed, the examiner stated that "while the claim may recite at least one of a vagina, introitus or vulva tissue are part of the target tissue, the other tissue treated in Knowlton are also considered as part of the female genital tissue." (February 13, 2014 Office Action at 13).

Regarding the remaining portion of Defendants' construction, the Court rejects it because it is overly broad. As discussed above, Defendants' construction reads the "therapeutic zone" out of the claim, and allows the "remodeling" to apply to any collagen tissue underlying the epithelium. As recited in the claim and indicated in the specification, the "therapeutic zone" is a zone within the target tissue. For example, the specification states that "[n]ot all tissue within the target tissue necessarily reaches this threshold level of heat. In some cases, cooling from the treatment tip may penetrate into the target tissue, and in this situation, the presence of cooled tissue may have an effect on the therapeutic zone, by moving it deeper within the target tissue, for example, or by constraining its volume." '511 Patent at 4:16–22. Defendants' construction incorrectly reads the "therapeutic zone" out of the claims, by equating the zone with any collagen tissue underlying the epithelium. As discussed above, the "therapeutic zone" is a zone of tissue within the target tissue that is heated to a therapeutic temperature.

The Court also rejects Defendants' construction because it further qualifies the "target tissue" as "collagen tissue." The specification states that "[t]he target tissue lies immediately beneath the mucosal epithelium of genital tissues, and includes the lamina propria, a connective tissue that includes collagen in the extracellular space, and the muscularis, which includes smooth muscle." '511 Patent at 3:43-47. Thus, the specification indicates that the "therapeutic zone" is not limited to "collagen tissue."

3. Court's Construction

The preamble limits the claims by requiring the target tissue to include tissue underlying an epithelium of female genital tissue that includes at least one of vulva, introitus and vagina tissue.

V. CONCLUSION

The Court adopts the constructions above for the disputed and agreed terms of the Asserted Patent. Furthermore, the parties should ensure that all testimony that relates to the terms addressed in this Order is constrained by the Court's reasoning. However, in the presence of the jury the parties should not expressly or implicitly refer to each other's claim construction positions and should not expressly refer to any portion of this Order that is not an actual construction adopted by the Court. The references to the claim construction process should be limited to informing the jury of the constructions adopted by the Court.

So ORDERED and SIGNED this 13th day of November, 2017.

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE

Court Exhibit A

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SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
HUPCZEY, JR, RONALD JAMES	

ART UNIT	PAPER NUMBER
3739	

NOTIFICATION DATE	DELIVERY MODE
02/13/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@shayglenn.com

Office Action Summary	Application No. 11/704,067	Applicant(s) PARMER, JONATHAN B.	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/15/2011*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-8,10-23 and 26-57* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-8,10-23 and 30-57* is/are rejected.

8)☒ Claim(s) *26-29* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *02/07/07* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *5/29/13, 9/26/13, 11/6/13*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 15th, 2011 has been entered. Currently, claims 1-8, 10-23, and 26-57 are pending with claims 1, 19, 21, 23, 26-31, and 41 amended, and claims 9, 24, and 25 cancelled. The following is a complete response to the April 15th, 2011 communication.

Notice of Pre-AIA or AIA Status

2. The present application is being examined under the pre-AIA first to invent provisions.

3. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5-8, 10-11, 13, 16, 18, 20, 22-23, 30-42, 45-46 and 49-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton et al (US Pat. No. 6,350,276).

Regarding claim 1, Knowlton discloses a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of the vulva, introitus and vagina tissue (as in the embodiment of figures 13-14 describing the treatment of cervix, see col. 13; 35-37; the Examiner notes that while Knowlton discusses the specific treatment of the cervix, the other tissues recited in the claim are also considered as part of the female genital tissue with the claim failing to specifically require that those portions comprising the target tissue are actually heat and/or remodeled), the method comprising heating the target tissue and remodeling the therapeutic zone of target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 5, Knowlton discloses that the heating comprises delivering energy by contacting the epithelium with a treatment tip (contact by template **12** and force application **14** contacting tissue surface **21**), the tip including an energy delivery element (energy delivery device **18** contained therein).

Regarding claim 6, Knowlton the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy (see col. 7; 52 – col. 8; 3).

Regarding claim 7, Knowlton discloses that the heating is controlled by a feedback control such that temperature does not go higher than a predetermined temperature (see at least col. 20; 66 though col. 21; 26).

Regarding claim 8, Knowlton discloses that the feedback control is provided by one or more thermal sensors (see at least col. 20; 66 though col. 21; 26.

Regarding claim 10, Knowlton discloses that the method further comprises cooling the epithelium (cooling of contact tissue **21** by the fluid **15** as in col. 5; 16 through col. 6; 4).

Regarding claim 11, Knowlton discloses that the cooling is by contacting the epithelium with a treatment tip wherein the tip includes a cooling mechanism (fluid **15** contacting tissue surfaces as in col. 5; 4-15 through the delivery of the fluid through device **10** to the contacting tip as would be in figures 13-14).

Regarding claim 13, Knowlton discloses that the method further comprises cooling of at least some of the target tissue, the cooling of the target tissue having an effect on the therapeutic zone (see col. 5; 16 – col. 6; 48 disclosing the extent and effect of the cooling provided by fluid **15**).

Regarding claim 16, Knowlton discloses that the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue (see col. 5; 52-59).

Regarding claim 18, Knowlton discloses that the method comprises contacting the epithelium with a treatment tip at a one or more contact sites during a procedure (see figure 3 showing the template **12** and surface **14** contacting the tissue surface **21** at a plurality of points during treatment), the tip comprising an energy delivery element adapted to heat the target tissue (energy delivery device within the template/surface).

Regarding claim 20, Knowlton discloses that the method includes contacting the tip to the epithelium at a plurality of contact sites (template **12** and surface **14** contacting multiple sites)

during a procedure and moving the tip from site to site wherein the combined contact sites comprising a treatment area (movement of the tip into contact with each of the sites contacted by template **12** and surface **14** containing energy device **18** to form a combined treatment area).

Regarding claim 22, Knowlton discloses that the method further comprising repeating the procedure one or more times (see col. 11; 65 – col. 12; 1 discussing the retreating and refining by using the procedure again).

Regarding claim 23, Knowlton discloses that the treatment areas of the one or more procedures, may be any of the same treatment area, different treatment areas, or overlapping treatment areas (refining of a previous treatment as in col. 11; 65 – col. 12; 1 would require the retreating of substantially the same area).

Regarding claim 30, Knowlton discloses that the target tissue includes submucosa and muscularis below the mucosal epithelium (see at least col. 3; 66 – col. 4; 14).

Regarding claim 31, Knowlton discloses that the heating does not substantially modify the mucosal epithelium of the genital tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64; it is noted that the without better defining what "substantially" means in the claim, the Examiner is interpreted the effects of the method of Knowlton to not be substantial).

Regarding claim 32, Knowlton discloses that remodeling comprises contracting target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claims 33 and 34, Knowlton discloses that the method described in claim 1 would include tightening the vagina and/or introitus (as displayed in figures 13 and 14 by the treatment of pre-term cervical dilation wherein the template **12** with energy device **18** treats the

cervix such that tightening occurs and the entire cervix is strengthened, see at least col. 13; 37-43).

Regarding claim 35, Knowlton discloses that the remodeling comprises denaturing collagen (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 36, Knowlton discloses that the remodeling comprises tightening collagen-rich sites in the target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 37, Knowlton discloses that the remodeling comprises rejuvenating the genital tissue toward a conformation like that which the genitalia had prior to experiencing vaginal birth (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64 and col. 13; 36-47).

Regarding claim 38, Knowlton discloses that at least some of the remodeling occurs during the heating (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 39, Knowlton discloses that at least some of the remodeling occurs after the heating (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 40, Knowlton discloses that the remodeling after the heating is by a depositing of collagen in the target tissue (see at least col. 14; 19-36 which discloses the induction of collagen formation due to heating).

Regarding claim 41, Knowlton discloses an apparatus for remodeling a therapeutic zone within a target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus, and vagina tissue (as in the embodiment of figures 13-14 describing the treatment of cervix, see col. 13; 35-37; the Examiner notes that while Knowlton discusses the specific treatment of the cervix, the other tissues recited in the claim are also considered as part of the female genital tissue with the claim failing to specifically require that those portions comprising the target tissue are actually heat and/or remodeled), the apparatus comprising a treatment tip (distal end of device **10**, see figures 1 and 2A), the tip comprising a shaft comprising a longitudinal axis (see figures 1 and 2a), an energy delivery element, (element **18**) and a cooling system (fluid **15** supplied to the distal end of device **10** via a lumen **13'**), wherein the energy delivery element is capable of contacting the epithelium (as shown and disclosed throughout as contacting tissue surface **21**) and wherein the treatment tip is configured to deliver energy from the energy delivery element to the target tissue in a uniform manner (see at least col. 7; 30- col. 8; 3 disclosing the application of energy).

Regarding claim 42, Knowlton discloses that the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft (see the structural arrangement of the energy elements **18** relative to the longitudinal axis of the shaft in figure 2A).

Regarding claim 45, Knowlton discloses that the energy delivery element is configured to be fiat (see the flat shape of the energy device **18** in figure 18B).

Regarding claim 46, Knowlton discloses that wherein the energy delivery element is configured to have a radial curvature with respect to the longitudinal axis of the shaft (see curved shape of energy device **18** as in figure 1).

Regarding claim 49, the shaft is configured to include a narrow portion proximal to the energy delivery element (narrow portion of the shaft of the device indicated at **10** distal to **10'** in figure 2A) wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft (see the structural arrangement of each of energy devices **18**), such that the energy delivery element projects forward from the shaft (energy devices **18** extending distally in figure 2A).

Regarding claim 50, Knowlton discloses that the cooling system is configured to cool the energy delivery element (fluid **15** being provided to energy element **18** via lumen **13'**).

Regarding claim 51, Knowlton discloses the cooling system comprises cooling fluid (fluid **15**) and at least one nozzle (opening of lumen **13'** spraying fluid onto device **18** as in col. 5; 10-15) the nozzle configured to spray the cooling fluid on the energy delivery element.

Regarding claim 52, Knowlton discloses that the energy delivery element comprises at least one capacitively coupled electrode (see col. 19; 28-29 discussing capacitive coupling).

Regarding claim 53, Knowlton discloses that the energy delivery element comprises at least one radiofrequency (RF) electrode (energy device **18** functioning to receive RF energy as in at least col. 7; 52 – col. 8; 10).

Regarding claims 54 and 55, Knowlton discloses that the RF electrodes function in either a monopolar or bipolar manner (see col. 15; 25- col. 16; 67)

Regarding claim 56, Knowlton discloses that at least one thermistor located in close proximity to the electrode (see col. 8; 31-50).

Regarding claim 57, Knowlton discloses that the system comprises a programmable memory chip (see col. 21; 15-25).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-4, 12, 14-15, 17, 19, 21, 43-44 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton et al (US Pat. No. 6,350,276).

Regarding claims 2-4, While Knowlton discloses various temperature ranges and energy density/delivery Knowlton fails to specifically recite the tissue to be heated the claimed ranges.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the target tissue to the claimed temperature ranges since the claimed temperature ranges are well known and commonly utilized temperature ranges in the art to provide the desired remodeling and thermal treatment disclosed in Knowlton. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the disclosed ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 12, Knowlton discloses that the cooling fluid applied to the epithelium is cooled to the temperature of -100 degrees Fahrenheit (see col. 5; 41-42) but fails to specifically recite that the epithelium comprises cooling it to a temperature between about 0 degrees C. and about 10 degrees C. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to cool the tissue to the temperature range claimed since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Additionally, in view of the disclosed cooling ranges and control system of Knowlton, one of ordinary skill in the art would readily appreciate the capability of the system to cool the epithelial surface to the claim temperature.

Regarding claims 14 and 15, Knowlton discloses a plurality of different heating and cooling algorithms (see col. 6; 5-7) but fails to specifically recite the cooling schemes of each of the claims. However, it would have been obvious to one of ordinary skill in the art in light of the disclosure in column 6 of Knowlton to provide cooling before, during and after the heating of the

tissue in order to successfully effectuate the desired treatment. In looking at the feedback system, temperature sensors and cooling system, one of ordinary skill would readily appreciate the desire to cool the tissue at each time to ensure that the tissue surface is never overheated thereby charring or burning the contact surface.

Regarding claim 17, Knowlton fails to specifically recite the temperature gradients produced in the various levels of tissue when utilizing a reverse thermal gradient cooling device. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reverse thermal gradient ranges from a low temperature of about 0 degrees C. to about 10 degrees C. at the epithelium to a high temperature of about 45 degrees C. to about 80 degrees C. in the underlying target tissue since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Knowlton discloses in col. 5; 52-59, the use of reverse thermal gradient devices which are known in the art and as such, one of ordinary skill, given the disclosed control system, temperature monitoring devices and feedback system would readily appreciate operating the system of Knowlton at the claimed ranges to effectuate the disclosed treatments to the tissue **9**.

Regarding claims 19 and 21, Knowlton discloses the monitoring of contact between the treatment tip of the device and the treatment surface **21** with a sensor to ensure that adequate contact is maintained during treatment (see at least cols. 19-20 discussing the monitoring of contact and impedance at the electrode sites) and the repeated treatment which is needed along with the use of multiple modalities of treatment to a target site (see col. 11; 65 – col. 12; 1). Knowlton fails to specifically recite the limitations of claims 19 and 21. However, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to contact one or more sites one or more times or contact any one site more than once during treatment in order to effectively provide the desired treatment to the tissue **9**. Repeated application of energy to a target portion of tissue is well known in the art and providing such a treatment step to the method of Knowlton would be a matter of mere routine experimentation by one of ordinary skill in order to obtain the desired result at the target area.

Regarding claims 43 and 44, Knowlton fails to recite the claimed sizes of the energy delivery element. However, one of ordinary skill in the art at the time the invention was made would readily appreciate providing an energy delivery device of the claimed size ranges since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Additionally, Knowlton discloses for the energy device **18** to have a plurality of different intended target sites and to work within a plurality of different energy density ranges which would require one of ordinary skill in the art to adjust the size of the energy device to a suitable size based on the desired treatment and energy density.

Regarding claims 47 and 48, while Knowlton in the embodiments of figures 1 and 2B show that the energy device **18** has a radius of curvature, Knowlton fails to disclose that the radius of curvature is up to or about 30 degrees. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a radius of curvature of up to or about 30 degrees in order to provide an energy device, template and surface which all conform to a desired treatment area. Additionally, in providing such a range, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or

workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It has also been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Allowable Subject Matter

10. Claims 26-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: With regard to each of claim 26-29, the Examiner has taken the position with respect to amended claim 1, that while the claim may recite at least one of a vagina, introitus or vulva tissue are part of the target tissue, the other tissue treated in Knowlton are also considered as part of the female genital tissue. The Examiner is also of the position that claim 1, as presently recited, fails to specifically require that those portions (vulva, vagina or introitus tissue) comprising the target tissue are actually required to be either heated or remodeled by the claim. Turning to the recitations in claims 26-29, each claim as amended presently requires that a portion of tissue not taught by Knowlton is heated in the method. That is, a specific portion of the vagina is required to be heated in each of claims 26 and 27, a portion of the genital tissue radiating outward from the introitus to Hart's line is required to be heated in claim 28, and a muscosal surface of the labia minora is required to be heated in claim 29. Knowlton has only ever set forth in col. 13, 35-37 that the circumference of the cervix is treated so as to contract a dilated cervical OS. This limitation fails to provide for the specific locations of heating recited in each of claims 26-29.

Furthermore, the Examiner has failed to find any other piece of prior art that fairly discloses, suggests, or makes obvious the treatment of those areas.

Response to Arguments

12. Applicant's arguments filed April 15th, 2011 have been fully considered but they are not persuasive.

13. Applicant has proffered arguments against the previously-filed rejection of claims 1, 5-8, 10, 11, 13, 16, 18, 20, 22-42, 45, 46, and 49-57 under 35 U.S.C. 102(b) as anticipated by Knowlton (US Pat. No. 6,350,276) on page 9 of the Remarks. Applicant argues with respect to each of independent claims 1 and 41 that Knowlton does not disclose a method for "remodeling a therapeutic zone including at least one of vulva, introitus or vagina" as presently recited in claim 1, or an apparatus "for remodeling a therapeutic zone underlying a mucosal epithelium of at least one member of the group vulva, introitus, and vagina". The Examiner, however, respectfully disagrees with Applicant.

It is the Examiner's position that the Applicant's amendments to each of claims 1 and 41 to which attempt further specify the type of tissue forming at least a part of the therapeutic zone fail to positively require that any of the tissue of the vulva, the introitus or the vagina is actually required to be heated and/or remodeled per claim 1. Similarly, the Examiner does not believe that the apparatus of claim 41 need to treat any of the tissue of the vulva, the introitus or the vagina. That is, the Examiner is of the position that the embodiment of figures 13-14 with the description of the treatment of cervix in col. 13; 35-37, fairly provides for the claimed method and apparatus. As has been noted above, it is the Examiner's position that while Knowlton discusses the specific treatment of the cervix, the other tissues recited in the claim are also

considered as part of the female genital tissue with each claim failing to specifically require that those portions comprising the target tissue are actually heat and/or remodeled. This lack of a positive requirement of the treatment of the presently-recited areas in claims 1 and 41 is due in part to each limitation's positioning within the preamble of each, claim, to the claiming that it is the female genital tissue which is comprising the tissue of the vagina, introitus or vulva, and to the lack of a close end to the tissue which can comprise the therapeutic zone.

In contrast, the Examiner points to the indication that claims 26-29 are allowable above. These claims have been indicated as allowable due to the fact that each actually requires the treatment of a portion of the female genital tissue (via heating a specific portion) which is not taught by Knowlton (i.e. not the cervix). Such positive claiming can be used as a guideline when drafting subsequent language.

As such, it is for at least the reasoning set forth above that the Examiner believes that the rejection of claims 1, 5-8, 10-11, 13, 16, 18, 20, 22-23, 30-42, 45-46 and 49-57 under 35 U.S.C 102(b) as unpatentable over Knowlton remains tenable. The Examiner further believes that these remarks above fully address Applicant's arguments on page 10 of the Remarks directed towards the previously proffered rejections of claims 2-4, 12, 14-15, 17, 19, 21, 43-44 and 47-48 under 35 U.S.C. 103(a). These arguments are only based on the alleged allowability of claims 1 and 41 as amended, these arguments having been addressed by the Examiner in the response above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/RONALD HUPCZEY, JR/
Primary Examiner, Art Unit 3739

RJH